FEB - 3 2012

510(k) Summary
(21 CFR Part 807.92)

Submitter Information

Submitter's Name:	Theken Spine, LLC
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Contact Person:	Dale Davison
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Date Prepared:	12/29/2011

Device Information

Trade Name:	Coral™ Spinal System
Common Name:	Pedicle Screw Spinal System
Classification:	**MNI** 888.3070 – Pedicle Screw Spinal System **MNH** 888.3070 – Pedicle Screw Spinal System **KWQ** 888.3060 – Spinal Intervertebral Body Fixation Orthosis **KWP** 888.3050 – Spinal Interlaminal Fixation Orthosis **NKB** 888.3070 – Spondylolisthesis Spinal Fixation System
Predicate Device:	Theken Surgical Coral™ Spinal System, K070962, K081414, K091266, K041592 SeaSpine, Inc. Malibu Spinal System, K061342
Device Description:	The purpose of this submission is the addition of the Malibu adjustable cross connector from SeaSpine Inc. to the Coral™ Spinal System. Cross connectors are used to connect the bi-lateral rods of a spinal construct to add torsional rigidity. The cross connectors are available in two styles, straight and contoured, the different styles offer the surgeon options intra-operatively. The straight cross connector offers the surgeon a low profile compared to the surrounding construct. The contoured cross connector offers surgeons an option that is slightly higher in profile but provides additional clearance between the cross connector and the spinal construct.
Intended Use:	The Coral™ Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.
Material Composition:	Implant grade titanium alloy Ti 6Al-4V (ELI) per ASTM F-136.

Comparison to predicate device

Substantial equivalency to the predicate device is based on the design concept; the use of established, known materials; feature comparisons; mechanical testing; indications for use; pre-production quality assurance planning and engineering analysis.

Similarities	Differences
Same indications for use	Contoured and non-contoured styles available
Same operating principle	Shorter overall length available
Manufactured from the same biocompatible materials	Fewer number of steps to implant
Same manufacturing environment	Fewer instruments required to implant
Same sterilization process	
Same packaging configuration	

Performance tests:

Static compression bending per ASTM F-1717
Static torsion per ASTM F-1717
Dynamic compression bending with run out per ASTM F-1717

Conclusion:

The conclusions drawn from the non-clinical tests demonstrate that the Malibu adjustable cross connector is as safe, as effective, and performs as well or better than the legally marketed predicate device Coral™ Spinal System adjustable cross connector.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

FEB - 3 2012

Theken Spine, LLC
% Mr. Dale Davison
1153 Medina Road
Medina, Ohio 44256

Re: K120047
Trade/Device Name: Coral™ Spinal System
Regulation Number: 21 CFR 888.3070
Regulation Name: Pedicle screw spinal system
Regulatory Class: Class III
Product Code: NKB, MNI, MNH, KWQ, KWP
Dated: December 29, 2011
Received: January 06, 2012

Dear Mr. Davison:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin L Keith

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K120047

The Coral™ Spinal System is a non-cervical spinal fixation device intended for use as a posterior pedicle screw fixation system, a posterior non-pedicle screw fixation system, or as an anterolateral fixation system. Pedicle screw fixation is limited to skeletally mature patients. The device is indicated as an adjunct to fusion for the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), spinal stenosis, deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis), tumor, pseudoarthrosis, and failed previous fusion.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K120047